

Docket Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane (Room 1061)  
Rockville, Maryland 20852

RE: Docket No. 00D-1543

Dear Sir or Madam:

December 18, 2001

In response to the FDA's publication in the Federal Register of its Proposed Guidance "Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures: Glossary of Terms", Becton Dickinson (BD) submits the following comments. BD is a worldwide manufacturer of medical devices whose corporate headquarters is located in Franklin Lakes, New Jersey. The definition for "Closed Systems" states "an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system". In many situations in industry access is not controlled by persons that are responsible for the content. Access is controlled by a security function typically within the Information Technology (IT) function. We believe the definition be changed to "an environment in which access is controlled by an Information Technology or other security function within the firm or by person(s) who are responsible for the content of electronic records that are on the system".

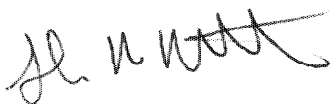
The definition for "Open System" we also suggest be modified to reflect the above suggestion: "an environment in which access is not controlled by an Information Technology or other security function within the firm or by person(s) who are responsible for the content of electronic records that are on the system".

We suggest adding in the definition for *person* "organization, department" as this would better define *person* within an end users firm.

In addition, we also would suggest changing the definition of "regression testing" by adding the word *subsequently*. The definition would read: "Rerunning test cases which a program has previously executed correctly in order to detect errors spawned by changes or corrections made during *subsequent* software development and maintenance. It may be also helpful to add in a definition for *test cases*.

We thank the agency for the opportunity to make comments on this pending Guidance document.

Sincerely,



Glenn M. Mattei, Esq.  
Director of Validation Services  
BD

00D-1543

C10